DEPARTMENT OF HEALTH AND HUMAN SERVICE
Public Health Service

Purged PKS 12/6/99 HFI-35 M3222N

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive Suite 400
New Orleans, LA 70127

Telephone: 504-253-4500
FAX: 504-253-4566

November 24, 1999

WARNING LETTER NO. 2000-NOL-06

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Brennon P. LeJeune, President
Aqua Farms Crawfish, Inc.
2364 Basile Eunice Highway
Basile, Louisiana 70515-3100

Dear Mr. LeJeune:

On May 3, 5, & 6, 1999, a U.S. Food and Drug Administration (FDA) investigator conducted an inspection of your crawfish processing facility, located at 2364 Basile Eunice Highway, Basile, Louisiana. The inspection was conducted to determine compliance with FDA's seafood processing regulations, Title 21, *Code of Federal Regulations* (CFR), Part 123 and the Current Good Manufacturing Practice (CGMP) regulations for foods CFR, Part 110. Our investigator documented numerous deviations from these regulations. This causes your finished ready-to-eat products, vacuum packaged crawfish, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act.

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the May 1999 inspection, the FDA investigator observed shortcomings in your system that were similar to those pointed out in the May 11, 1998, inspection performed by the Louisiana Department of Health and Hospitals, Seafood Sanitation Unit, and stated in the untitled letter sent to your firm on July 14, 1998. The FDA investigator also provided your firm with a copy of the Domestic Seafood HACCP Report (Form FDA 3501) and the Form FDA 483, which presents his evaluation of your firm's performance regarding various

aspects of the HACCP and CGMP requirements. The Form FDA 483 is enclosed for your review. The observations of concern to us are as follows:

- Failure to identify the peeling step as a CCP for time/temperature control of the significant hazard pathogen growth, as required by Title 21, CFR, Part 123.6(b).

  The critical control point begins when a cooked, ready-to-eat product is further handled or contacts surfaces that were not heated along with the product. At this point, time above a critical temperature becomes a critical limit and must be monitored.

- Failure to address the hazard of Clostridium botulinum in your HACCP plan for vacuum packaged crawfish tails, as required by Title 21, CFR, Part 123.6(c)(1).

  Freezing is an appropriate control for the hazard of Clostridium botulinum growth and toxin formation in your vacuum packaged peeled crawfish tailmeat. However, the label must also contain the wording "keep frozen, thaw under refrigeration immediately before use" or " keep frozen, break seal before thaw" to ensure the safety of your product. Your HACCP plan should list the Clostridium botulinum hazard with freezing as the control.

- Failure to have adequate sanitation monitoring records e.g., the records for May 5, 1999, do not include monitoring of the employees, toxic compounds and hand iodine/chlorine solutions, as required by Title 21, CFR, Part 123.11(b); and,

- Failure to document corrective actions taken when sanitation deficiencies were noted, as required by Title 21, CFR, Part 123.11(c).

Objectionable equipment and insanitary conditions as listed on Form FDA 483 and Form FDA 3501 are an indication that sanitation monitoring [21 CFR, Part 123.11(b)] at the firm is inadequate. Calling your attention to the objectionable insanitary conditions in this letter is in the interest of having your firm improve its sanitation program consistent with the HACCP principles. A failure to make appropriate corrections could cause your HACCP processing system to be found unacceptable during a future FDA inspection. The noted objectionable insanitary conditions include the following:

- Twenty-one peeling employees did not wash and sanitize their hands prior to the start-up of the peeling operation;

- The iodine solution in the peeling room, at the start of peeling operations, was of inadequate strength;

- No sanitizing solution was available to the cook room employees;

- Employees routinely handled unsanitary items such as: hoist controls, doors, walls, residues on doors, walls and concrete floor, and live crawfish; then handled cooked crawfish without first washing and sanitizing their hands and gloves; and,

- A live fly was noted in each of the two crawfish peeling rooms and one dead fly was noted in the ice used in making the ice/water slush.

As the principal corporate officer, it is your responsibility to assure that your processing plant is operating in compliance with the applicable laws and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that adequate policies and procedures are implemented to prevent a recurrence of the problems.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the applicable regulations. You should take prompt action to correct these deviations. Failure to promptly correct the deviations may result in regulatory action without further notice. These include seizure and/or injunction.

We are aware that at the close of the inspection you made a verbal commitment to correct the observed deficiencies. Our investigator documented this commitment by annotation of the FDA Form 483. You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply, relating to these concerns, should be addressed to the U.S. Food and Drug Administration, Attention: Patricia K. Schafer, Compliance Officer, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. If you have any questions regarding the implementation of the HACCP regulations, you may contact Ms. Schafer at (504) 253-4500.

Sincerely,

James E. Gamet
District Director
New Orleans District

Enclosure: FDA-483